PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LL04PCT002	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. **PCT/KR2004/001358**	International filing date *(day/month/year)* **07 JUNE 2004 (07.06.2004)**	Priority date *(day/month/year)* 10 JUNE 2003 (10.06.2003)

International Patent Classification (IPC) or national classification and IPC

IPC7 A61K 38/22

Applicant

LG Life Sciences Ltd. et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demamd	Date of completion of this report
10 JANUARY 2005 (10.01.2005)	11 JULY 2005 (11.07.2005)
Name and mailing address of the IPEA/KR Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer LEE, Mi Jeong Telephone No. 82-42-481-5601

Form PCT/IPEA/409 (cover sheet) (January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/KR2004/001358

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☒ This report is based on translations from the original language into the following language English, which is the language of a translation furnished for the purposes of:

   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☒ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this reort as "originally filed" and are not annexed to this report):*

   ☒ the international application as originally filed/furnished

   ☐ the description:
   pages _____ as originally filed/furnished
   pages* _____ received by this Authority on _____
   pages* _____ received by this Authority on _____

   ☐ the claims:
   pages _____ as originally filed/furnished
   pages* _____ as amended (together with any statment) under Article 19
   pages* _____ received by this Authority on _____
   pages* _____ received by this Authority on _____

   ☐ the drawings:
   pages _____ as originally filed/furnished
   pages* _____ received by this Authority on _____
   pages* _____ received by this Authority on _____

   ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages _____
   - ☐ the claims, Nos. _____
   - ☐ the drawings, sheets _____
   - ☐ the sequence listing *(specify)* : _____
   - ☐ any table(s) related to sequence listing *(specify)* : _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages _____
   - ☐ the claims, Nos. _____
   - ☐ the drawings, sheets _____
   - ☐ the sequence listing *(specify)*: _____
   - ☐ any table(s) related to sequence listing *(specify)* : _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/KR2004/001358

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4 - 11	YES
	Claims	1 - 3	NO
Inventive step (IS)	Claims		YES
	Claims	1 - 11	NO
Industrial applicability (IA)	Claims	1 - 11	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents are referred to here:

D1: EP 0909564 A1 (21 April 1999)
D2: WO 00/61169 (19 October 2000)

1. Novelty

Claims 1-3 of the present invention are related to erythropoietin solution preparations containing human erythropoietins (natural or obtained by genetic recombination); nonionic surfactants (polysorbates, poloxamers), polyhydric alcohols (propyleneglycols, polyethyleneglycols, glycerols), neutral amino acids (glycine, alanine, leucine, isoleucine) and sugar alcohols (mannitol, sorbitol, inositol) as stabilizers; isotonic agents (NaCl, CaCl2, Na2SO4); buffer solutions (phosphate buffer, citric acid buffer), and they are free from human serum albumins as a stabilizer.

D1 discloses an erythropoietin solution preparation containing human erythropoietins (natural or obtained by genetic recombination); polysorbates; polyethyleneglycol; L-leucine; sugar alcohols such as mannitol, sorbitol, and inositol; isotonic agents such as NaCl, CaCl2 etc.; sodium citrate, and they are free from human serum albumins and purified gelatins.
As described before, the ingredients of the erythropoietin preparation in D1 are the same as those in Claims 1-3 of the present invention.

Therefore, Claims 1-3 of the present invention cannot be considered to be novel over D1 (Article 33(2) PCT).

2. Inventive Step

Since the novelty of Claims 1-3 cannot be acknowledged, the inventive step of Claims 1-3 cannot be acknowledged, either.

Claim 4 of the present invention relates to a specific erythropoietin solution preparation containing an erythropoietin, polysorbate 20, propyleneglycol, glycine, mannitol, NaCl, phosphate buffer,
(Continued on Supplemental Box.)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Box V.

free from human serum albumins.

D2 discloses aqueous pharmaceutical formulations of erythropoietin that are free of human serum blood products, stabilized with a quantity of an amino acid such as glycine, L-leucine, L-isoleucine etc. and a sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivative such as polysorbate 80.

Claim 4 of the present invention and D1 differ only in the kind of an amino acid as a stabilizer. But the erythropoietin preparation in D2 contains a glycine as well as L-leucine as a stabilizer. Those who skilled in the art would be able to easily exchange the leucine in D1 with the glycine in D2. Therefore, the inventive step of Claim 4 cannot be acknowledged over D1 and D2.

Claims 5-11 of the present invention specified the amount of each ingredient in the said preparations in Claim 1.
Once all the ingredients of the erythropoietin solution preparations are determined from D1, specifying the optimal amount of each ingredient in the said preparations in Claims 5-11 can be easily done from the general knowledge of those who skilled in the art.
Therefore, Claims 5-11 of the present invention do not involve an inventive step over D1 (Article 33(3) PCT).

3. Industrial Applicability

The subject-matter of Claims 1-11 appears to be industrially applicable (Article 33(4) PCT).